



2024 FSASC Quality & Risk Management Conference
April 4, 2024
Regulatory Update

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Objectives

- Update on the Risk Management Process
- Review of the top federal ASC tags
- Discuss two ASC survey case examples
- Agency Updates



Update on the Risk Management Survey Process



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Pending Updates to the Survey Process

- Independent Risk Management Survey Process **Or**
- In conjunction with recertification/relicensure or complaint.
 - sampling of incident reports for review, and sampling for staff interviews and training file reviews are reduced
- More patient centered outcome-oriented survey process.



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Entrance Conference

- Conduct meeting with the ASC Administration/Risk Manager/Risk Manager Designee.
- Present the Risk Management Entrance Checklist to facility Administration and explain the requested facility documents and information need to be provided as soon as possible.



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Entrance Conference, cont.

- Introduce survey team members.
- Request additional information to address facility issues, complaints and risk management concerns as provided during the off-site preparation.



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Tour

- The objective of this task is to observe the ASC where areas of concern have been identified to determine the compliance with the Risk Management regulations.
- Conduct **brief** observations and interviews related to the identified concerns during this tour.



Sample Selection and Information Gathering

- Sample Selection and size will depend.
- Information Gathering
 - Observations
 - Staff Interviews
 - Patient and Family Interviews
 - Patient Record Reviews
 - Facility Record/System Review
 - Personnel Records



Decision Making and Exit Conference

- The objective of this task is to integrate findings, review and analyze information collected from observations, interviews, and record reviews, and to determine whether the ASC is in compliance with the rules and regulations.
- The exit conference provides an opportunity for the surveyor to discuss areas of concern with the administrator and/or staff in charge.



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Review of the top federal tags



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ASC Top Federal Health Tags- CY 2021

Tag	Title	Regulatory Reference
Q0181	Administrations of Drugs	416.48(a)
Q0162	Form and Content of Records	416.47(b)
Q0241	Sanitary Environment	416.51(a)
Q0266	Discharge Order	416.52(c)(2)
Q0184 & Q0262	Verbal Orders & Admission and Pre-Surgical Assessment	416.48(a)(3) & 416.52(a)(2)



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ASC Top Federal Health Tags- CY 2022

Tag	Title	Regulatory Reference
Q0181	Administrations of Drugs	416.48(a)
Q0241	Sanitary Environment	416.51(a)
Q0266	Discharge Order	416.52(c)(2)
Q0101	Physical Environment	416.44(a)(1)



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ASC Top Federal Health Tags- CY 2023

Tag	Title	Regulatory Reference
Q0266	Discharge- Order	4126.52(c)(2)
Q0181	Administration of Drugs	416.48(a)
Q0101	Physical Environment	416.44(a)(1)
Q0162	Form and Content of Records	416.47(b)



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Immediate Jeopardy Findings



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ASC Case Example – Immediate Jeopardy

- June 7, 2023- Complaint (State and Federal)
- Conditions for Coverage: Q0040- Governing Body and Management And Q0060 Surgical Services
- The facility failed to ensure the endoscopy procedures were performed by licensed and qualified staff.
- During the procedure the patient was screaming in pain, asking the staff to stop. Staff continued with the procedure.
- Administrative staff were aware and failed to intervene to protect the patients.



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ASC Case Example - Immediate Jeopardy

- August 22, 2023 – Complaint (State and Federal)
- Condition for Coverage Q0060 Surgical Services and Q0219 Patient Rights
- The facility failed to ensure surgical procedures were performed by qualified personnel in a safe manner.
- The facility failed to ensure that patients were informed of the unlicensed surgical technologists suturing surgical incision outside of their scope of practice.
- The facility failed to ensure that patients were fully informed of facility practices related to the closure of surgical wounds.



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Agency Updates And Data



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Adverse Incident Reporting- Reminders

395.0197 Internal risk management program.—

- (5) For purposes of reporting to the agency, the term “adverse incident” means an event over which health care personnel could exercise control, and which is associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred, and which:
 - (a) Results in one of the following injuries:
 1. Death;
 2. Brain or spinal damage;
 3. Permanent disfigurement;
 4. Fracture or dislocation of bones or joints;
 5. A resulting limitation of neurological, physical, or sensory function which continues after discharge from the facility;



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Adverse Incident Reporting- Reminders.

6. Any condition that required specialized medical attention or surgical intervention resulting from nonemergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent; or

7. Any condition that required the transfer of the patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the patient's condition prior to the adverse incident;

- (b) Was the performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition;
- (c) Required the surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process; or
- (d) Was a procedure to remove unplanned foreign objects remaining from a surgical procedure.



AHCA Incident Reporting System (AIRS) CY 2023

Number of Adverse Incidents

Year	Outcome Text Short	AMBULATORY SURGICAL CENTER				Grand Total
		Q1	Q2	Q3	Q4	
2023	Death	2	2	4	4	12
	Limit Function				2	2
	Medically Unnecessary	1	1		2	4
	No Consent	4			1	5
	Remove Foreign Objects	1	2	1	2	6
	Surgical Repair	1	4	2	2	9
	Transfer	7	8	24	15	54
	Unrelated Surgery		1	4	2	7
	Wrong Patient Surgery		2		1	3
	Wrong Site Surgery	4	7	3	8	22
	Wrong Surgery	1	4	5	3	13
Grand Total		21	31	43	42	137



AHCA Incident Reporting System (AIRS) 2024 Q1

Number of Adverse Incidents

Year	Outcome Text Short	AMBU LATO..	Grand Total
		Q1	
2024	Death	2	2
	Limit Function	1	1
	No Consent	1	1
	Surgical Repair	2	2
	Transfer	18	18
	Unrelated Surgery	1	1
	Wrong Site Surgery	1	1
	Wrong Surgery	1	1
Grand Total		27	27



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Have Questions??

- Please contact the Office of Risk Management and Patient Safety directly at (850) 412-3731, or by email at riskmgmtps@ahca.myflorida.com
- [Office of Risk Management and Patient Safety \(myflorida.com\)](https://myflorida.com)



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Complaint Data

- CY 2022
 - Investigated: 46
 - Substantiated: 16
 - Common Substantiated Allegations: Life Safety, Quality of Care and QAPI
- CY 2023
 - Investigated: 40
 - Substantiated: 13
 - Common Substantiated Allegations: Falsification of Records, Unqualified Personnel, Adverse Incidents not reported timely, and QAPI.



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Patient Safety Culture Survey (PSCS) Program

- Section 395.1012, F.S. requires the Agency to collect PSCS data biennially from hospitals and ambulatory surgical centers
- Rule 59A-35.115, FAC providing specific requirements became effective January 26, 2023
- The initial reporting period will be **June 1 – August 31, 2025.**
- Additional information is available at:
<https://ahca.myflorida.com/schs/commiteescouncils/indexpscs.shtml>



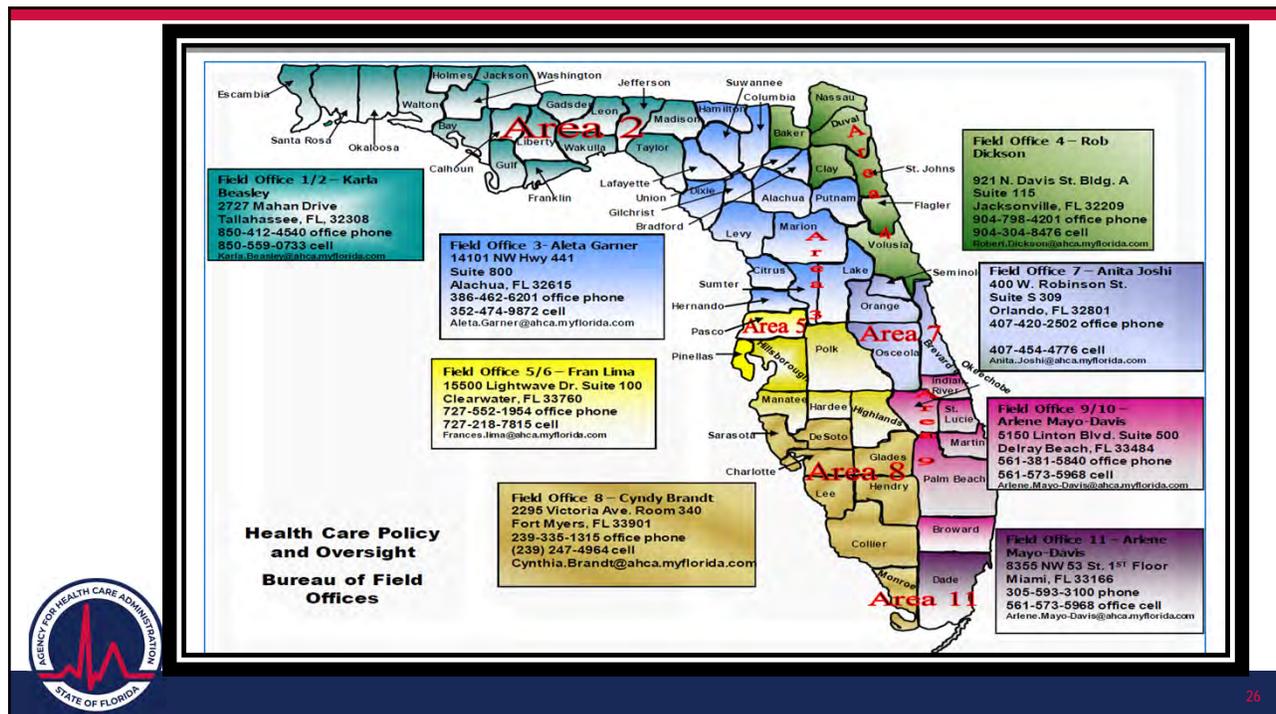
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HB 7089- Health Care Expenses (Transparency)

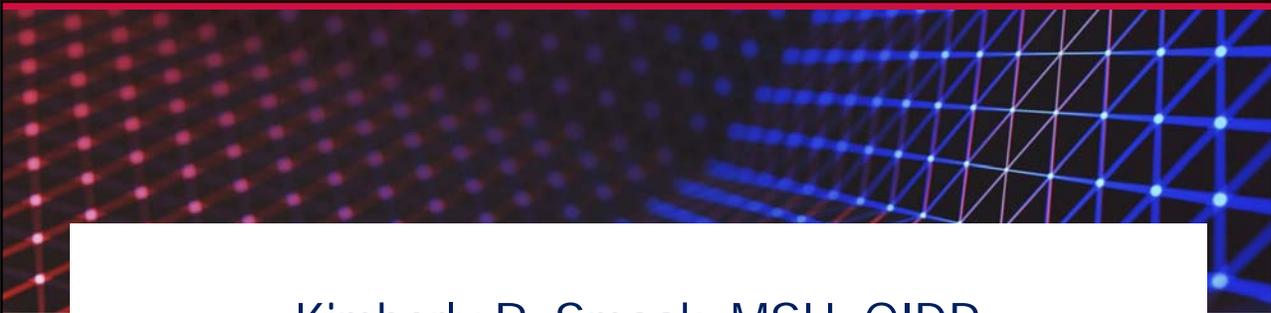
- 395.301 Price transparency:
 - Facilities must post standard charges for shoppable services. (ASCs 1/1/2026, & Hospitals 7/1/2024)
 - Provide estimates in advance.
 - Establish an internal process for reviewing and responding to grievances from patients.
 - Must allow a patient to dispute charges that appear on the itemized statement or bill.
 - Respond to grievance within seven days.



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